JUL 15 2002

K020968

510k Submission for the Pan Probe Biotech, Inc. LiveSure™ Human Chorionic Gonadotropin (LiveSure™ hCG) Rapid Urinary Pregnancy Test Immunoassay Devices

Pan Probe Biotech, Inc.

Revised July 11, 2002

SUMMARY OF SAFETY AND EFFECTIVENESS

Pan Probe Biotech, Inc., has developed, manufactured, and tested, under Good Laboratory Practices guidelines, both Test Strip and Test Card *in vitro* diagnostic (IVD) devices for rapid qualitative testing of urine samples for the presence of human Chorionic Gonadotrpin (hCG) related to pregnancy at an Expected Value cut-off level of 20 mIU of hCG/ml of urine. The IVD medical device trade names are the Pan Probe Biotech or PPB LiveSure™ hCG Screen Test Strip and Test Card Devices, having FDA assigned name: Human Chorionic Gonadotrpin (hCG) Test Systems, and classified as Class II device per 21 CFR 862.1155, with product code: DHA.

The PPB LiveSure™ hCG Screen (i.e., LiveSure™ hCG) Test Strip and Test Card Devices are rapid qualitative lateral flow chromatographic IVD immunoassays and are intended for professional IVD use only. The Pan Probe Biotech LiveSure™ hCG Test Strip & Test Card Devices provide only preliminary analytical data for use to aid in the diagnosis of pregnancy. A clinical diagnosis by a medical professional must be obtained in order to confirm any analytical result. Each test device consists of a sample reaction unit, a pink colored colloidal gold conjugate unit pre-labeled with hGC-specific mouse-monoclonal antibody, and a chromatographic membrane was precoated with mouse-anti-alpha-hCG capture antibodies at the test band region and goat-anti-mouse antibody at the process control band region. During the test, the human urine specimen is allowed to react with hCG-specific mouse-monoclonal antibody-colloid gold conjugate, which has been predried on the test component of each device. The mixture then moves chromatographically upward on the membrane by the capillary action. For a pregnancy-positive specimen, gold conjugate complex binds to hCG at a level of 20 mIU/ml or greater, forming an antibody-antigen complex. This complex binds to hCG antibody as captured regents on the Test Region and produces a colored band when hCG concentration is equal to or greater than 20 mIU/ml. Absence of this colored band in the Test Region suggests a negative result Summarizing, negative urine will produce only one pink colored band in the control region, while positive urine will produce two pink colored bands, in both the control and test regions.

In-house and external testing of LiveSure™ hCG Test Strip and Test Card Devices was done against currently marketed predicate hCG test devices, including: ABI's SureStep™ hCG Test and Quidel's QuickVue™ hCG Assay devices, as well as the quantitative Abbott's Axsym™ hCG EIA assay. Against clinical lab data on diagnoses of pregnancy, and against each other results, statistical agreement was obtained between LiveSure™ hCG IVD Test Strip and Test Card Devices versus the predicate ABI's SureStep™ and Quidel's QuickVue™ hCG Test IVD devices. In particular, complete agreement was obtained for 3 main statistical parameters: a) for relative sensitivity with positives pregnancy tests (100%), b) for relative specificity or agreement with negative pregnancy diagnoses (100%), and c) for over-all accuracy >99%, both at an independent clinical lab (testing 252 urine samples with clinically confirmed diagnoses and run by several licensed technologists), as well as by in-house testing of 136 urine samples (also with clinically confirmed diagnoses). Comparison of the same 252 urine assay results for both PPB LiveSure™ hCG Test Strip & Test Card Devices against quantitative hCG Axsym™ EIA Assay determinations at the external independent clinical lab resulted in: a) 100% percent agreement for relative sensitivity of positive EIA results, but relative specificity 153/161or 95.0% for EIA negatives, and an over-all statistical accuracy of 244/252 or 96.8%. The same statistical results were obtained for the ABI's SureStep™ and Quidel's QuickVue™ hCG Test devices, as well as versus the clinical lab diagnoses data of pregnancy. These results were thought to be due to 8 low EIA values out of 252 independent lab specimens and 5 low EIA negatives out of 136 in-house samples, all determined to be below 15 mIU/ml by the Axsym™ EIA method. These low Axsym™ EIA results were concluded to be False Negatives by EIA, since the same patients were independently confirmed to be clinically pregnant. Against this clinically pregnancy data, there was 100% positive agreement versus predicate ABI's SureStep™ and Quidel's QuickVue™ hCG Test devices results as well as for both PPB LiveSure™ hCG Test Strip and Test Card devices, both in-house and at the external independent clinical laboratory.

Thus, compared to independent clinically Positive diagnoses of pregnancy, these studies found that both PPB LiveSure™ hCG Test Strip and Test Card devices were substantially equivalent in performance to approved predicate ABI's SureStep™ and Quidel's QuickVue™ hCG test devices, as well as to the quantitative Axsym™ EIA assay results. Additionally, compared to independent Negative diagnoses of pregnancy, these studies showed that both PPB LiveSure™ hCG Test Strip and Test Card devices were substantially equivalent in performance to approved predicate ABI's SureStep™ and Quidel's QuickVue™ hCG test devices, and gave results that were 95% or better in equivalency to the quantitative Axsym™ EIA assay results. Substantial equivalency versus these two predicate IVD devices was thus confirmed for both PPB LiveSure™ hCG Test Strip and Test Card IVD devices.

Additional information on this submission may be obtained by contacting Alice Yu, Vice President, Pan Probe Biotech, Inc. at 1- 858-689-9936 or by fax at 1-858-689-6896.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 15 2002

Pan Probe Biotech, Inc.
c/o Alfredo J. Quattrone, Ph.D., D.A.B.T.
Medical Device Safety Section
California Department of Health
Food & Drug Branch
P.O. Box 942732 (MS-357)
Sacramento, CA 94234-7320

Re: k020968
Trade/Device Name: LiveSure™ hCG Urinary Pregnancy Test Strip and Test Card
Regulation Number: 21 CFR 862.1155
Regulation Name: Human chorionic gonadotropin (HCG) test system
Regulatory Class: Class II
Product Code: JHI
Dated: June 28, 2002
Received: July 1, 2002

Dear Dr. Quattrone:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): 21 CFR 862.1155; Prod. Code: DHA

DEVICE NAME: Pan Probe Biotech (PPB), Inc. LiveSure™ Human Chorionic Gonadotropin (LiveSure™ hCG) Rapid Urinary Pregnancy Test Strip and Test Card Immunoassay Devices

INDICATIONS FOR USE STATEMENT:

Pan Probe Biotech (PPB), Inc. LiveSure™ Human Chorionic Gonadotropin (LiveSure™ hCG) Rapid Urinary Pregnancy Test Strip and Test Card Immunoassay Devices are *in vitro* diagnostic (IVD) qualitative screening lateral flow chromatographic immunoassays that are designed for rapid detection of placental hCG related to pregnancy at an expected value cut-off level of 20 mIU of hCG/ml of human urine. These LiveSure™ IVD immunoassay devices for urinary hCG pregnancy screening are designed to give visual, qualitative results and are intended for professional use only. The PPB LiveSure™ hCG Test Strip and Test Card Devices are not intended for quantitative results, nor over-the-counter sales, but provide only professional use preliminary screening data for use to aid in the diagnosis of pregnancy. A clinical diagnosis by a medical professional must be obtained in order to confirm any analytical result, and to rule out any non-pregnancy diseases that can also result in elevated hCG. Clinical considerations and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020968

Prescription Use: ✓ **or** **Over-the-Counter Use:** _____
(Per 21 CFR 801.109) **(Optional Format 1-2-96)**